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Research Article

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Correlation of FeNO With FeV1 and Other Biomarkers in Predicting Severity of Asthma

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ABSTRACT

Asthma is a chronic respiratory condition characterized by airway inflammation. It is often classified into phenotypes such as Type 2 and non-Type 2 asthma, each with distinct inflammatory markers. This study focused on assessing FeNO, a non-invasive marker of airway inflammation, its association with other biomarkers (absolute eosinophil count (AEC), and serum IgE level) and asthma severity, as measured by forced expiratory volume in one second (FEV1%). This observational study was conducted in the Department of Respiratory Medicine, AIMSR Bathinda. 163 asthma patients aged 18 to 65 years were included. FeNO levels correlated positively with AEC and IgE levels, suggesting that these biomarkers rise with increased airway inflammation. However, a weak negative correlation was observed between FeNO and FeV1%, implying that higher FeNO levels may reflect greater asthma severity but do not directly correspond with lung function. The study concluded that while FeNO, AEC, and IgE are valuable biomarkers for evaluating airway inflammation, they should be considered together to comprehensively assess asthma. This multidimensional approach supports personalized asthma care, where treatment is tailored according to each patient's unique clinical presentation and biomarker profile. This study highlights the need for future research on composite biomarker scores and potential of artificial intelligence to enhance asthma diagnostics, paving the way for improved patient outcomes in asthma management.

INTRODUCTION

Asthma is a major global health issue impacting both adults and children with increasing prevalence rates, high healthcare demands and varied mortality across different countries. Asthma's prevalence is influenced by age and income level, with higher rates in high-income countries. As of 2019, asthma contributed 21.6 million disability-adjusted life years (DALYs) and ranked 34th in disease burden worldwide, with India bearing a significant portion of this load due to delayed diagnosis and treatment [1].

The Global Initiative for Asthma (GINA) defines asthma as a chronic airway inflammation causing symptoms such as wheezing, shortness of breath, and coughing, with variable expiratory airflow limitation, often triggered by factors like allergens, exercise, or pollution.[2]

Asthma varies widely, with different phenotypes, such as all -ergic and non-allergic types, that require different treatment appr -oaches. Type 2 inflammation, common in allergic asthma, results from immune response where interleukins activate immune cells, leading to airway remodelling, mucus production and hyper respon -siveness. Non-Type 2 asthma, characterized by neutrophilic infla-mmation, may be influenced by environmental factors like pollution or smoking [2,3].

Asthma diagnosis depends on symptom history and expiratory airflow variability tests since there's no definitive test. Biomarkers such as blood eosinophils, serum IgE, and exhaled nitric oxide are promising for precise diagnosis and treatment. Blood eosinophil levels, though influenced by other conditions, can indicate airway inflammation in severe cases. IgE levels help identify allergic asthma and guide targeted treatments, such as anti-IgE therapy, which has shown efficacy in reducing exacerbations and improving quality of life [4,5].

The classification of asthma is based on severity and response to treatment, ranging from mild (managed with low-dose medication) to severe (requiring high-dose or specialized therapies). Personalized approaches and precision medicine, focusing on biomarkers, have the potential to advance asthma management by tailoring treatment according to individual patient profiles [6].

Nitric oxide (NO) in the lungs is produced both enzymatically and

non-enzymatically by neurons, vascular endothelial cells, and epithelial cells. Enzymatic NO production in the airways involves the conversion of L-arginine by nitric oxide synthase (NOS) isoforms neuronal (nNOS), endothelial (eNOS), and inducible (iNOS) each with distinct roles, such as inflammation suppression by nNOS and immune defense by iNOS. In asthma, altered NO production, particularly via iNOS, is linked to airway inflammation. [7] High fractional exhaled NO (FeNO) levels suggest eosinophilic inflam - mation, while low FeNO levels point to other conditions like Rhinosinusitis, Noneosinophilic asthma, Reactive airways dysfunction syndrome, COPD, Bronchiectasis. FeNO testing, ideally at a 50 ml/s expiratory flow rate, is a valuable diagnostic tool in assessing asthma severity and predicting response to steroid treatment. Elevated FeNO levels, typ - ically over 50 ppb in adults and 35 ppb in children, indicate uncontrolled asthma, often requiring therapy adjustments [8,9].

Beyond FeNO, biomarkers like periostin are linked to airway inflammation, smooth muscle function, and treatment response in asthma. Additionally, non-Type 2 markers like sputum neutrophils highlight the role of neutrophilic inflammation, common in non-type 2 asthma and linked to treatment resistance [10,11].

Biomarkers help to refine asthma diagnosis, prognosis, and therapy. FeNO aids in stratifying asthma risk, with high levels linked to exacerbations and ICU visits. Ongoing research emphasizes "biomarker trajectories" to track asthma progression, integrating digital health tools for more frequent assessments. Biomarker guided therapy, using FeNO and eosinophil levels, supports personalized ICS dosing, especially in severe cases. The concept of treatable traits specific asthma features addressed by tailored treatments combined with pharmacogenomics, shows promise in optimizing asthma management. Overall, these advanc ements support a personalized, data driven approach to improve asthma outcomes and patient quality of life [12,13].

The aim of this study was to examine the correlation between various biomarkers and asthma severity. Specifically, the objectives were to assess fractional exhaled nitric oxide (FeNO) levels and absolute eosinophil count (AEC) in asthma patients and to establish, if any clinical correlation exists between FeNO levels, AEC, serum IgE levels and asthma severity as measured by forced expiratory volume in one second (FEV1).

MATERIAL AND METHODS

This prospective observational study was conducted at the Department of Respiratory medicine, Adesh institute of Medical Science and Research, Bathinda, over a period of 18 months. Ethical approval was obtained from the Institute's Ethical Approval Committee of Biomedical and Research Committee.

The study population consisted of all bronchial asthma patients aged 18 to 65 years, who visited the outpatient department (O.P.D) at AIMSR Bathinda's Respiratory Medicine Department during the study period. 163 patients were selected who met the inclusion criteria. Patients in whom spirometry was contraindicated, such as those with haemoptysis or pneumothorax or infections; as well as smokers, obese patients, pregnant women and those with lung cancer or COPD or cardiovascular conditions and those who had undergone any recent surgeries were excluded from the study.

After informed consent, patients were grouped based on their Spirometry findings, severity of symptoms and step of treatment as per GINA guidelines. Past history of exacerbations was also recorded. Patients were divided into Mild, moderate and severe asthma based on their FEV1%. Those with FEV1% is >80 were categorized as mild, those with FEV1% of 60-79 were categorized as moderate and those with FEV1% is <60 were categorized as severe asthma.

FeNO levels were measured using FeNOM. For the Purpose of this study, FeNO levels were divided into three categories - FeNO <25, FeNO 25- 49 and FeNO>50.

S. IgE was measured using CLIA technique and in this study, we have divided the S. IgE into three categories i.e. 1 - 190 IU/ml, 191- 499 IU/ml and >500 IU/ml

Complete Blood Counts were done in all patients. Ab - solute Eosinophil count was calculated by % of eosinophils x TLC count. AEC has been divided into two categories i.e. <350/cumm and >350/cumm.

Data Analysis:

Data analysis involved recording and coding data in Microsoft Excel. Demographic variables were analyzed with frequencies and percentages and represented in bar, pie, and line charts. Statistical methods included the Z-test for comparing findings, chi-square test for trend associations, and Spearman's correlation test to assess relationships. A significance level of $p<0.05$ was set to determine statistical relevance.

RESULTS

163 asthma patients were enrolled in the study between September 2022 and March 2024. Participants underwent four clinical tests: FeNO, S. IgE, AEC. Of the 163 patients, 47% (n= 78) were female and 53% (n=85) were male.

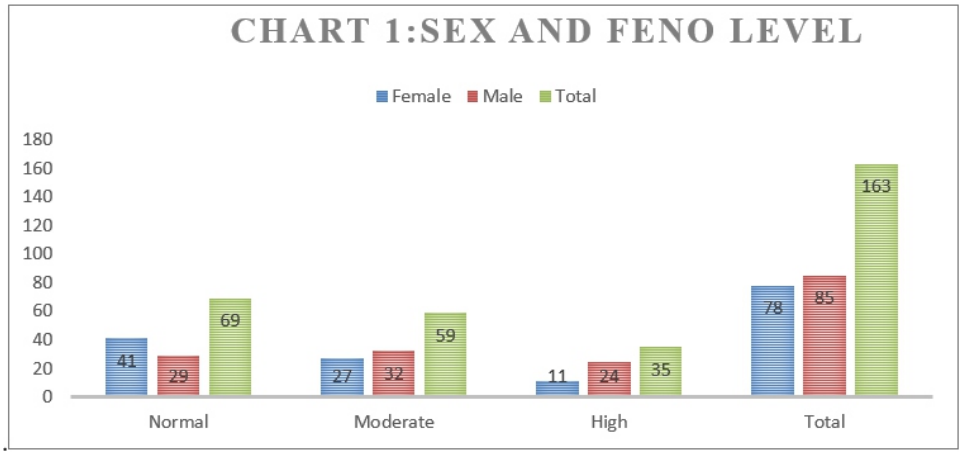
21% (n=34) were between 18 to 30 years, 29% (n=48) between 31-45 years, 23% (n=39) between 46-60 years, and 26% (n=42) were aged >60 years.

FeNO levels were categorized into normal (<25), mode - rate (25-49), and high (>50). Based to table 1, the majority of the normal FeNO group was over 60; moderate levels were spread across ages, while high levels were concentrated in patients aged 31-60 years.

Table 1: Distribution of FeNO Level According to Age

Age Level	FeNO Level			
	Normal (<25)	Moderate (25-49)	High (>50)	Total
18 - 30 Years	11 (15.9)	15 (25.4)	8 (22.9)	34 (20.86)
31-45 Years	20 (29.0)	17 (28.8)	11 (31.4)	48 (29.45)
46-60 Yrs.	16 (23.2)	11 (18.6)	12 (34.3)	39 (23.92)
Above 60 Yrs.	22 (31.9)	16 (27.1)	4 (11.4)	42 (25.77)
Total	69 (100.0)	59 (100.0)	35 (100.0)	163 (100.0)

52.5% (n= 41) of females and 34.1% (n = 29) of males in the study in the study had normal FeNO levels, according to the gender distribution of FeNO levels shown in Chart 1. Of those in the intermediate group, 37.6% (n=32) were men and 34.5% (n=27) were women. Interestingly, compared to 28.2% (n= 24) of males, 14.0% (n= 11) of females exhibited elevated FeNO levels. Male patients were more likely to have increased FeNO than female patients,



The study classified serum IgE (S. IgE) into normal (1-190 IU/ml), high (191- 499 IU/ml), and very high (>500 IU/ml) categories. Findings revealed that 38% of part - icipants had normal S. IgE, 29% had high levels, and 33% had extremely high levels.

Additionally, the study (Table 2) reveals that around 44% of females have normal S. IgE levels, compared to just 33% of males; whereas 23% females and 35% males have high level of S. IgE and 33% of the females and 32% males have extremely high level of S. IgE.

Table 2: Sex and S.IgE Level

S.IgE Level	Sex		
	Female	Male	Total
Normal <190	34 (43.6)	28 (32.9)	62 (38.0)
High 190 - 499	18 (23.1)	30(35.3)	48 (29.5)
Extremely High >500	26 (33.3)	27(31.8)	53 (32.5)
Total	78 (100.0)	85 (100.0)	163 (100.0)

The statistical analysis of the 163 patients, provided key insights: the mean FeNO was 38.83 the mean S. IgE was significantly higher at 1149.19, the mean AEC was significantly higher at 543.94, and the mean FEV1 was 66.80.

The correlations with FeNO showed weak positive relatio nships with S. IgE (r = 0.18) and AEC (r = 0.20), but a negative correlation with FEV1% (r = -0.23). These findings suggest complex interrelations between asthma biomarkers.

Table 3: Statistical Inferences of FeNO, S. IgE, AEC, FEV1

Statistical Rsults	FeNO	S.IgE	AEC	FEV1/FVC	FEV1%
Number (N)	163	163	163	163	163
Mean (M)	38.82822	1149.188	543.9387	66.80804	65.81166
Std. Deviation	33.17343	1864.224	578.9263	12.66678	16.73141
Correlation (r) of FeNO with		0.178639	0.20131	-0.23343	-0.21032

Further the Table 4 shows that when the FeNO level is normal, the trend of S. IgE continuously falls down i.e. number of cases decrease as S.IgE levels goes from normal (39 cases) to very high (13 cases), but when the FeNO level reaches moderate and high level this trends of S.IgE reverses and shows an increasing tendency.

Table 4: Correlation of FeNO and S. IgE Level

FeNO Level	S.IgE Level			
	Normal	High	extremely High	Total
Normal	39 (62.9)	17 (35.4)	13 (24.5)	69 (42.33)
Moderate	16 (25.8)	21 (43.8)	22 (41.5)	59 (36.20)
High	7 (11.3)	10 (20.8)	18 (34.0)	35 (21.47)
Total	62 (100.0)	48 (100.0)	53 (100.0)	163 (100.0)

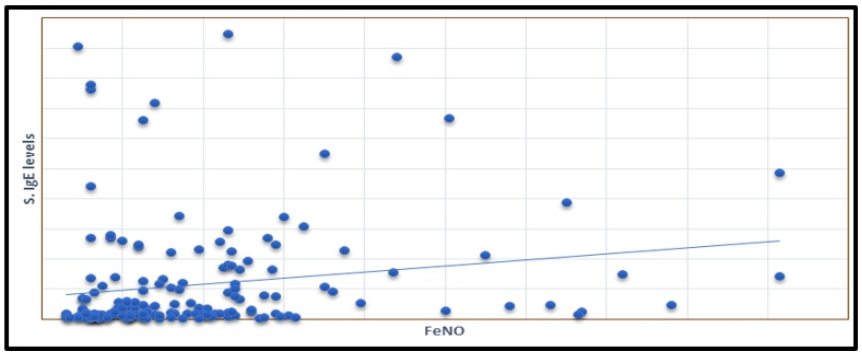


Figure 1: Correlation of FeNO and S.IgE

The analysis of the table 4 shows that FeNO and S. IgE test are independent of each other, even though there is a weak positive correlation ® being just 0.18 i.e. very close to zero level i.e. no relationship situation) as shown by figure: 1. Hence, the change in FeNO has no unidirectional relationship with the change in S. IgE, even though it is marginally positive.

Table 5: Correlation of FeNO and AEC Level

Feno Level	AEC		
	Normal <350	High >350	Total
Normal	45 (54.9)	24 (29.6)	69 (42.33)
Moderate	28 (34.1)	31 (38.3)	59 (36.20)
High	9 (11.0)	26 (32.1)	35 (21.47)
Total	82 (100.0)	81 (100.0)	163 (100.0)

AEC is categorized into normal (<350) and high (>350) levels. Among the 163 samples studied, 82 were normal, and 81 were high, indicating an even distribution. Notably, while the correlation coefficient (r) of 0.2 indicates a positive, albeit weak, correlation between FeNO and AEC. This suggests that though AEC in the normal range corresponds with lower FeNO levels, an increase in AEC is associated with a rise in moderate and high FeNO levels as depicted by Figure: 2.

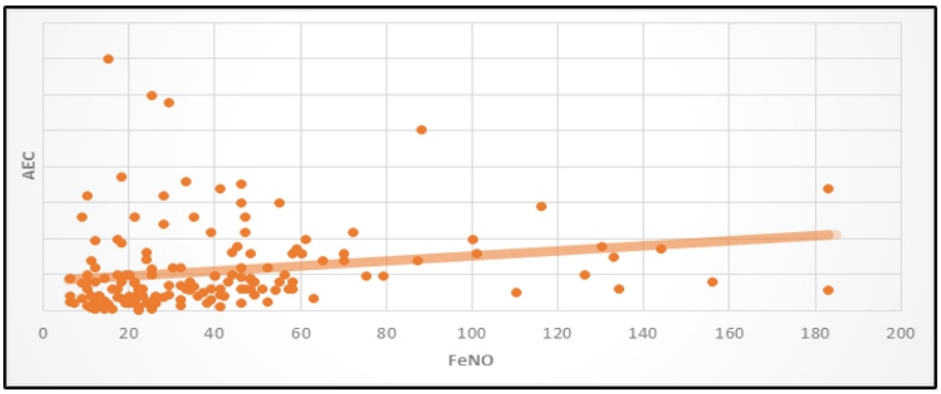


Figure 2: Co-relation of FeNo and AEC

The relationship between FeNO levels and FEV1% is crucial for assessing asthma severity. FEV1% is categorized as mild (>80), moderate (60-79), or severe (<60). The study indicates that even with normal FeNO levels, asthma severity can vary, and high FeNO does not exclusively correlate with severe asthma; mild and moderate cases can also occur at high FeNO levels. However, the incidence of severe asthma tends to increase as FeNO levels rise.

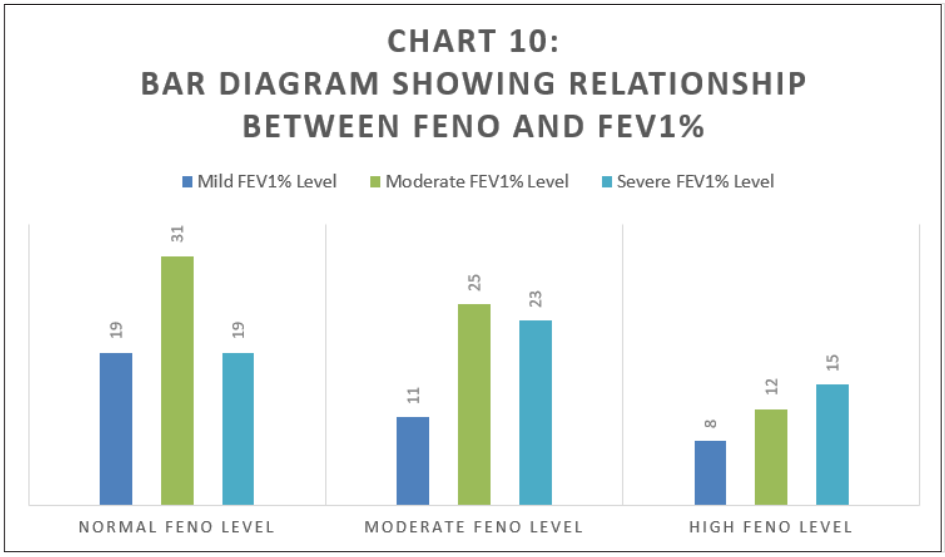


Figure 3: Bar Diagram Showing Relationship between FeNO and FeV1%

Table 6: FeNO Level with FeV1%

FeNO Level	Severity of Asthma: FEV1% Level			
	Mild	Moderate	Severe	Total
Normal	19 (50.0)	31 (45.6)	19 (33.3)	69 (42.33)
Moderate	11 (28.9)	25 (36.8)	23 (40.4)	59 (36.20)
High	8 (21.1)	12 (17.6)	15 (26.3)	35 (21.47)
Total	38 (100.0)	68 (100.0)	57 (100.0)	163 (100.0)

In the analysis of table: 6 and figure: 4 indicates that FeNO and FEV1% are independent tests, as higher FeNO levels generally correlate with a decrease in FEV1% across most categories. Therefore, they exhibit a negative corre - lation; however, it is weak, as the correlation coefficient (r) of -0.2 is close to zero on the scale.

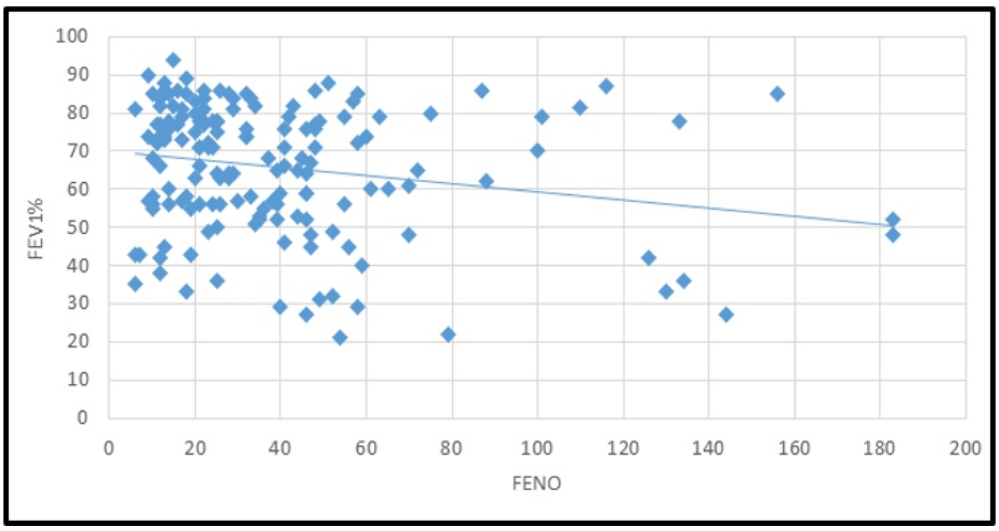


Figure 4: Co-relation of FeNO with FeV1%

DISCUSSION

The Global Initiative for Asthma (GINA) defines asthma as a heterogeneous disease marked by chronic airway inflammation and symptoms like wheezing, breathlessness, chest tightness, and coughing, which vary in severity over time [13]. In India, asthma affects around 34.3 million people, making up over 13% of the global asthma burden, with a prevalence of 6.6% in adults, 11% in adolescents, and 9.1% in children [14].

Asthma diagnosis relies on clinical history and spirom - etry to assess variable expiratory airflow limitation, which is essential in evaluating disease severity. Biomarkers, defined as measurable indicators of biological processes, are increasingly used to study severe asthma by categorizing phenotypes and endotypes, improving diagnostics, guiding treatment, and predicting responses. Type 2 inflammation, involving Th2 cytokines like IL-4, IL-5, and IL-13, has been a particular focus in asthma biomarker research. [15,16].

The relationship between FeNO and FEV1% (a measure of asthma severity) was a key focus in our study. FEV1% categorizes asthma severity into mild (>80%), moderate (60-79%), and severe (<60%) cases. Our study examined correlation of FeNO with asthma severity. Patients with asthma symptoms were enrolled after screening based on clinical criteria. Among 163 asthma patients (57% male, 43% female), the average age was 45.1 years, and the mean FeNO level was 38.82 ppb, with 57% of participants displaying FeNO >25 ppb. The average AEC was 543 cells/mm^3, with around half of the patients having AEC levels above 350 cells/mm^3, and 62% showing S. IgE levels above 190 IU/ml.

A weak negative correlation was observed between FeNO and FEV1% ($r = -0.21$, $p < 0.00001$),, indicating that higher FeNO levels, which may signal airway inflammation, are associated with lower FEV1% values, reflecting greater asthma severity. This relationship is complex. Additionally, a positive but weak correlation was noted between FeNO and AEC ($r = 0.2$, $p < 0.00001$) as well as between FeNO and S. IgE ($r = 0.18$, $p < 0.00001$). These findings suggest that FeNO correlates positively with both AEC and S. IgE, implying that these biomarkers may increase alongside airway inflammation.

Our findings indicate that while FeNO is a valuable marker, it is independent of FEV1%, AEC and S. IgE levels, each of which offers unique insights into asthma management. The weak correlations suggest that FeNO, AEC, and S. IgE should not be viewed in isolation but as part of a comprehensive asthma assessment. This supports the need for a multi-faceted diagnostic approach that considers each patient's distinct biomarker profile and clinical presentation, facilitating more personalized asthma care [17, 18].

The implications of our study emphasize several points for clinical practice and research. First, a personalized approach to asthma treatment is crucial, as each biomarker provides distinct information about disease activity and inflammation. Relying solely on FeNO or any other single marker may overlook the complex pathophysiology underlying asthma. Second, future research should investigate composite biomarker scores that integrate FeNO, AEC, and IgE, potentially yielding more accurate assessments of asthma control and risks of exacerbation. Longitudinal studies could further clarify how biomarker relationships evolve over time and in response to treatment, guiding dynamic adjustments in therapy. Additionally, exploring non-Type 2 inflammation biomarkers is essential for characterizing asthma phenotypes that might respond differently to standard treatments [19, 20].

Moreover, integrating multiple biomarkers could streamline asthma monitoring and offer real-time insights into airway inflammation. Cost-effectiveness is another consideration; while multi-biomarker assessment enhances diagnostic precision, its economic impact should be evaluated in healthcare systems, particularly in resource-constrained settings. [21, 22].

Lastly, artificial intelligence and machine learning hold promise for identifying complex patterns in biomarker data, potentially refining asthma severity predictions and improving patient outcomes [23, 24].

CONCLUSION

The study found that higher FeNO levels correlated positively with AEC levels and S. IgE levels (indicating increased airway inflammation) while negatively with FEV1% (signifying more severe asthma). While FeNO remains a useful tool, its role is most effective when integrated with other parameters. Our study emphasizes the importance of a multi-dimensional approach to asthma assessment, combining clinical and laboratory findings to capture the complexity of this chronic condition. As asthma research advances, so too should our diagnostic and therapeutic strategies, moving towards personalized asthma care that optimally addresses the diverse needs of patients. This approach can improve the quality of life and outcomes for the millions affected by asthma, supporting the broader goals of individualized medicine [25, 26].

Future multi-center studies with larger samples are required to further explore these biomarker interactions so as to refine personalized asthma care.

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